

GFP.

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cont*

45. (New) The expression vector of claim 39 or 44, wherein the GFP is a *Renilla* GFP.

REMARKS

Claims 13-37 were previously under consideration. Claims 19, 21, 22, 24, 25, 27, and 30-33 have been amended. Claims 38-45 have been added. Accordingly, claims 13-45 are presently under examination.

Cancellation of and/or amendment to the claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The cancellation of and/or amendments to the claims are being made solely to expedite prosecution of the above-identified application. Applicant reserves the option to further prosecute the same or similar claims in the instant or in another patent application.

Support for the above amendments can be found in the specification and claims as originally filed and/or previously pending. No new matter has been added. A version of the claims showing changes made is presented as Appendix A.

RESTRICTION REQUIREMENT

In the restriction requirement set forth in the Office Action mailed November 26, 2002 the Examiner required restriction between one of the following inventions:

Group I: Claims 13-20, 25-31, 34-37, drawn to an expression vector comprising nucleic acid encoding HBEGF and GFP, classified in class 435, subclass 320.1.

Group II: Claims 21-24, 32-33, drawn to an expression vector comprising a nucleic acid encoding a HBEGF and nucleic acid encoding IRES site, classified in class 435, subclass 320.1.

It is the position of the Examiner that these inventions are distinct from each other because Groups I and II inventions are distinct as they are not disclosed as capable of use together and have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). The examiner further states that the inventions of Group I and Group II are structurally and functionally distinct from each other and restriction between the groups is proper.

The examiner further states that, as these inventions are distinct for the above reasons, the search required for Group I is not required for Group II, and they have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Finally, the examiner claims that, even though the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive. Therefore, the examiner states that these do not create an undo search burden, and restriction for examination purposes as indicated is proper.

Applicant provisionally elects Group II, *with traverse*, for prosecution on the merits.. Applicant's grounds for traversal is set forth below.

Applicants traverse the restriction requirement to the extent that groups I and II should be reformed as a single group containing claims 13- 45 (referred to hereinafter as "*newly formed Group I*"). Applicants grounds for traversal are set forth below.

It is respectfully submitted that Applicant has presented an allowable generic claim, new claim 38, which is generic to the claims set forth in groups I-II proposed by the Examiner. New claim 38 is drawn to an expression vector comprising a first and a second selection gene, wherein the first and second selection gene are fused such that transcription from a promoter operably linked to the first selection gene results in a single transcript encoding the first and second selection genes and further comprising a site which allows for functional separation of the two selection genes, wherein the first selection gene is an HBEGF gene.

It is Applicants' position that given the presence of claim 38, which is generic to groups I-II proposed by the examiner a restriction under 35 U.S.C. §121 is improper. In view of the above traversal, Applicants hereby elect *newly formed Group I*, claims 13-45.

It is Applicants' position that while a species election may be proper among groups I and II for prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable, an election under 35 U.S.C. §121 is improper since the claims are linked by an allowable generic linking claim. Claim 38 embraces the species of expression vectors comprising HBEGF as a selection gene and a second selection gene (e.g., GFP), wherein the first and second selection gene are fused such that transcription from a promoter operably linked to the first selection gene results in a single transcript encoding the first and second selection genes and further comprising a site which allows for functional separation of the two selection genes. If a species election is required, Applicants further provisionally elect Group II for search purposes only. It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

Moreover, Applicants respectfully disagree with the position of the Examiner and argue that, contrary to the Examiner's position, Groups I and II are disclosed as capable of being used together (see, e.g., claim 25 or 38). In addition, as Groups I and II are of the same class and subclass, a literature search of both Groups I and II would be nearly, if not completely, co-extensive. Thus, examination of the claims of Groups I and II would not constitute an undue burden to the Examiner.

Applicants are further requested to elect a single species for each of the following:

- a) either 2a site or CD9 site;
- b) one single species of selection gene;
- c) one single species of GFP.

Applicants point out that the 2a site and the CD9 site, both of which can be additional components of the expression vector, are not related as species. CD9 is a diphtheria receptor (HBEGF) accessory protein. The 2a site and the IRES site, in contrast, are both species of sites which allows for separation of the two selection genes. For the purposes of being responsive Applicant elects, under 35 U.S.C. 121, the 2a site for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 17, 18, 19, 25, 33, 38, 39, 41, 42, and 43 are readable on this species. It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

In addition, the term "selection gene" as defined in the specification means a reporter gene that by its presence in a cell (i.e., upon expression) can allow the cell to be distinguished from a cell that does not contain the reporter gene. Therefore, HBEGF, GFP, drug resistance genes, and additional selection genes are all selection genes. For the purposes of being responsive Applicant elects, under 35 U.S.C. 121, GFP as the species of additional selection

gene for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 22, 32, 44, and 45 are readable on this species. It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

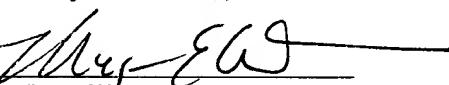
Applicant elects, under 35 U.S.C. 121, *Renilla mulleri* GFP as the species of GFP for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 13-20, 22, 30, 39, 44, and 45 are readable on this species. It is Applicants' understanding that the search will be extended to the remaining species upon a finding of allowability.

Applicants believe no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. RGV-003 from which the undersigned is authorized to draw. A duplicate of this sheet is enclosed.

Dated: January 27, 2003

Respectfully submitted,

By


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APPENDIX A**VERSION SHOWING CHANGES MADE**

19. **(Amended)** An expression vector according to claim 13 or 17 further comprising: a) [a] an additional selection gene.

20. **(Amended)** An expression vector according to claim 14 or 18 further comprising a promoter of interest [fused] operably linked to said nucleic acid encoding said HBEGF.

21. **(Amended)** An expression vector comprising: a first and second selection gene, wherein the first and second selection gene are fused such that transcription from a promoter operably linked to the first selection gene results in a single transcript encoding the first and second selection genes and further comprising an IRES site interposed between the first and second selection genes which allows for functional separation of the two selection genes, wherein either the first or second selection gene is an HBEGF gene.

- [a] nucleic acid encoding HBEGF;
- b) nucleic acid encoding an IRES site].

22. **(Amended)** An expression vector according to claim 21 further comprising [: a] an additional selection gene.

24. **(Amended)** An expression vector according to claim 21 further comprising a promoter of interest [fused] operably linked to said nucleic acid encoding said HBEGF.

25. **(Amended)** An expression vector comprising from 5' to 3':

- a) a nucleic acid encoding HBEGF;
- b) a 2a site;

c) a nucleic acid encoding GFP;

d) an IRES site; and

e) a promoter of interest.

27. **(Amended)** An expression vector according to claim 25 further comprising [a] an additional selection gene downstream of said IRES site.

30. **(Amended)** An expression vector according to claim 31 [28 further comprising a GFP] wherein said additional selection gene downstream of said IRES site encodes GFP.

31. **(Amended)** An expression vector according to claim 28 further comprising [a] an additional selection gene downstream of said IRES site.

32. **(Amended)** An expression vector according to any one of claims [claim 19,] 22, 27, or 31, wherein said additional selection gene is a drug resistance gene conferring resistance to drugs selected from the group consisting of puromycin, neomycin, blastocidin, bleomyhcin, and hygromycin.

32. **(Amended)** An expression vector according to any one of claims 22, 27, or 31, wherein said additional selection gene is a drug resistance gene conferring resistance to drugs selected from the group consisting of puromycin, neomycin, blastocidin, bleomyhcin, and hygromycin.

33. **(Amended)** An expression vector according to claim [20] 24, 25, or 28, wherein said promoter of interest is an IL-4 ϵ promoter.